

AUG 12 2003

510K SUMMARY

K 032146

Summary of Safety and Effectiveness

Prepared July 11, 2003

General Provisions

Submitter of 510(k): Precision Vascular
 Premarket Notification: 2405 West Orton Circle
 West Valley City, UT 84119
 Phone: 801.974.1700
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Contact Person: Rick Gaykowski
 Vice President, Regulatory/Clinical Affairs
 & Quality Systems

Device Trade Name: PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**®
 0.010" Guidewires

Device Generic Name: Guide Wire

The predicate devices are listed in the table below.

Predicate Devices

Device	Manufacturer	510(k) Number, Concurrence Date	Product Code
Synchro ™ .014"	Precision Vascular	K002907, 08 Mar 2001	DQX
Synchro ™ .010"	Precision Vascular	K023700, 04 Dec 2002	DQX
Transend-14	Target Therapeutics	K964611, 28 Jan 1997	DQX
Agility-14	Cordis	K001033, 14 Apr 2000	DQX
MTI Silverspeed	Micro Therapeutics	K001454, 07 Jun 2000	DQX
Transend-10	Target Therapeutics	K964611, 02 May 1996*	DQX
Agility-10	Cordis	K991646, 20 Jul 2000	DQX
Mirage .008"	Micro Therapeutics	K002212, 03 Aug 2000	DQX

* This information is assumed based on our best, current knowledge.

Classification Class II, 21 CFR 870.1330, Wire, Guide, Catheter 74DQX

Performance Standards Performance standards have not been established by FDA under section 514 of the Federal Food, Drug and Cosmetic Act.

Intended Use

The PVS 1300 **Synchro**® 0.014" & 1600 **Synchro**® 0.010" Neuro Guidewire series of products are intended for general intravascular use, which includes peripheral and neurovascular use. The device can be used to selectively introduce and position catheters and other interventional devices within the peripheral & neurovasculature. The device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

Device Description

The PVS 1300 & 1600 devices are members of the **Synchro**® guidewire family of products having a 0.014" & 0.010" outside diameter respectively, being sterile, single use/disposable products, with shapeable tip which is used to gain intravascular access

to and facilitate the positioning and exchange of interventional devices in small diameter, tortuous vasculature for peripheral, neuro diagnostic and interventional procedures. The guidewire can be torqued to facilitate navigation through the vasculature. A torque device, (Merit Medical Systems (K936032)) is supplied with the wire to facilitate deployment & positioning. A guidewire introducer (B. Braun (K760389)) is also supplied and may be used to aid introduction of the guidewire into the catheter hub and/or hemostasis valve and to gently shape the guidewire's distal flexible tip, if desired, according to standard practice. Neither the guidewire introducer or the torque device are intended to enter the body. The products are projected to be provided in a 180cm – 300cm length range, with 200cm being nominal. The Nitinol tip length is projected to be presented in a 25cm – 65cm range, with 35-45cm being nominal. A traditional range of flexibility profiles shall also be provided, ranging from support (stiff) to flex (soft). The device is coated on the outer diameter with a lubricious coating over the distal segment of the device. The marker coil is platinum wire at the distal tip of the device to aid visualization under fluoroscopy. The subject device has the ability to access distal, tortuous vasculature, with steerability and torque transmission properties.

Technological Characteristics

Technological similarities between the PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" guidewires and the cited **Synchro**™ predicates remain identical. This is also true for competitive predicate device features including the basal design and dimensions, generic materials & construction, and hydrophilic coating. There are no new questions raised regarding safety or efficacy of the PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" guidewires.

Safety and Performance Tests

Biocompatibility of the PVS 1300 **Synchro**® 0.014" Guidewire materials have been verified in accordance with ISO 10993-1, Biological Evaluation of Medical Devices - Part 1. Materials test results confirmed biocompatibility of the subject device when tested as an external communicating, blood contact, short duration (<24 hours) device.

Performance testing of materials comprising the PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" guidewires was conducted in accordance with ISO 11070:1998, Sterile, Single-Use Intravascular Catheter Introducers. Verification testing for the subject device included dimensional inspection, fatigue assessment, tip flexibility, tip shaping, tensile strength, guide wire compatibility testing and performance under simulated conditions. Subject product testing has yielded acceptable safety & performance outcomes.

In addition, torsional strength, torqueability, and corrosion resistance tests also yielded acceptable results. The results of these tests, in conjunction with the substantial equivalence claims as outlined in the premarket notification, effectively demonstrate the PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" guidewires' substantial equivalence to the cited predicate devices.

Summary of Substantial Equivalence

Based on the indications for use, technological characteristics, and safety and performance testing, the subject PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" guidewires meet the minimum requirements that are considered adequate for their intended use and are substantially equivalent in design, materials, sterilization, principles of operation and indications for use to current commercially available guidewires/cited predicates.

Class III Certification

This section is not applicable to the subject PVS 1300 **Synchro**[™] 0.014" & PVS 1600 **Synchro**® 0.010" devices, nor the cited predicates, since these products have been classified under Class II.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 12 2003

Precision Vascular, Inc.
c/o Mr. Rick Gaykowski
Vice President, Regulatory/Clinical Affairs and Quality Systems
2405 West Orton Circle
West Valley City, UT 84119

Re: K032146

Trade Name: PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" Guidewires
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guidewire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: July 11, 2003
Received: July 14, 2003

Dear Mr. Gaykowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

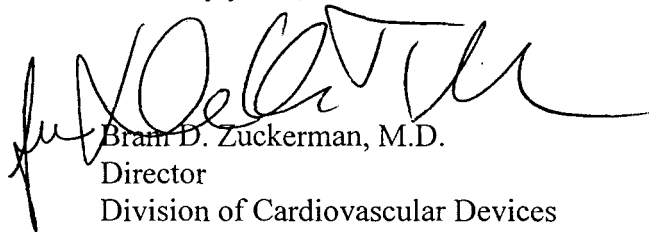
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or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Brian D. Zuckerman", is written over the printed name and title.

Brian D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" Guidewire

Indications for Use:

The PVS 1300 **Synchro**® 0.014" & PVS 1600 **Synchro**® 0.010" Guidewire series of products are intended for general intravascular use, including the neuro and peripheral vasculature. The device can be used to selectively introduce and position catheters and other interventional devices within the peripheral and neurovasculature. This device should be used only by physicians trained in percutaneous, intravascular techniques and procedures.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number

12032146

Prescription Use ☒

(Per 21 CFR 801.109)

OR

Over-the-Counter Use ☐